



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

June 14, 2017

Stephen Uden, M.D., Senior Vice
President Research
Alexion Pharmaceuticals, Inc.
100 College Street
New Haven, CT 06510

SUBJECT: ALEXION PHARMACEUTICALS, INC., LICENSE AMENDMENT, MAIL
CONTROL NO. 594704

Dear Dr. Uden:

This refers to your license amendment request dated May 4, 2017. Please find enclosed Amendment No. 20 authorizing animal studies for fluorine 18, copper 64, and gallium 68.

An environmental assessment for this action was not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please contact me at 610-337-5366 or via electronic mail at dennis.lawyer@nrc.gov so that appropriate corrections or answers can be provided.

You will be periodically inspected by the NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action(s) against you. This could include issuance of a Notice of Violation, or Imposition of a Civil Penalty, or an Order Suspending, Modifying or Revoking Your License as specified in the NRC Enforcement Policy. The NRC Enforcement Policy is available at:
<http://www.nrc.gov/reading-rm/doc-collections/enforcement/>.

An electronic version of the NRC's regulations is available on the NRC Web Site at: www.nrc.gov. Additional information regarding use of radioactive materials may be obtained on the NRC Web Site at: <http://www.nrc.gov/materials/miau/mat-toolkits.html>. This site also provides the link to the toolbox for updated information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web Site at: <http://www.nrc.gov/about-nrc/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

S. Uden

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In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web Site at: <http://www.nrc.gov/reading-rm/adams.html>.

Thank you for your cooperation.

Sincerely,

A handwritten signature in black ink, appearing to read "Dennis R. Lawyer", with a long, sweeping horizontal flourish extending to the right.

Dennis R. Lawyer
Commercial, Industrial, R&D
and Academic Branch
Division of Nuclear Materials Safety
Region I

License No. 06-28799-01
Docket No. 03032976
Mail Control No. 594704

Enclosure:
Amendment No. 20

cc: Joseph Paradiso, CSP, Director, Environmental Health and Safety

S. Uden

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Thank you for your cooperation.

Sincerely,

Dennis R. Lawyer
Commercial, Industrial, R&D
and Academic Branch
Division of Nuclear Materials Safety
Region I

License No. 06-28799-01
Docket No. 03032976
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Enclosure:
Amendment No. 20

cc: Joseph Paradiso, CSP, Director, Environmental Health and Safety

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SUNSI Review Complete: DLawyer

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